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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	PAPER NUMBER
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,718	WALDMANN ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-10,12-15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6-10, 12-15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 December 2008 has been entered.

2. Claims 2-5 and 11 are cancelled.

3. Claim 16 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. Claims 1, 6-10, 12-15 and 17 are under consideration.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

6. The provisional rejection of claims 1, 6-10, 12-15 and 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-41 of copending Application No. 09/979,948 (now US Patent 7,465,790) is withdrawn in view of the terminal disclaimer filed 12/19/2008 and approved on 1/9/2009.

7. The rejection of claims 1, 6-10, 12-15 and 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as introducing new matter is withdrawn in view of the amendments to the claims.

Objections/Rejections Maintained

8. The objection to the disclosure as containing sequences that are encompassed by the sequences rules (37 C.F.R. §§ 1.821-1.825) and require sequence identifiers is maintained.

The response filed 12/19/2008 still does not address this requirement to comply with the sequence rules raised in the Office Action mailed 8/4/2006 and as such the objection is maintained for reasons already of record (e.g., see item nos. 6-8 of the Office Action mailed 8/4/2006).

9. The rejection of claims 1, 6-10, 12-15 and 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 12/19/2008 reiterates that those skilled in the art understand readily that different antibodies will have different antibody combining sites, and that the location of the antibody combining site of an antibody can be determined by routine experimentation. Once the antibody combining site has been determined, one can modify the antibody by binding a peptide to the antibody combining site of the antibody by means known to those skilled in the art. In other words, once one skilled in the art has read what the modified antibody includes, one skilled in the art would be able to make the modified antibody by standard techniques known to those skilled in the art. Once the modified antibody is constructed, one skilled in the art would be able to determine through routine experimentation whether the peptide reduced binding of the antibody to the therapeutic target and reduced side effects caused by the antibody. Applicant concludes that the specification provides a written description of the invention. Applicants' arguments have been fully considered but are not found persuasive for the reasons already of record and reiterated herein for convenience. Applicants' argument that one skilled in the art could determine the antibody combining site for different antibodies, modify the antibody by binding a peptide to the antibody combining site and determine whether the peptide reduced binding of the antibody to the therapeutic target and reduced side effects caused by the antibody seems to go more toward enablement

than description. That is, the argument seems intended to show that, following the teachings in the specification, those skilled in the art could have produced other therapeutic antibody-peptide pairs, and determined which (if any) would have the claimed properties, without undue experimentation. The instant rejection is based on lack of adequate written description, not lack of enablement. The written description requirement is separate and distinct from the enablement requirement. I*n re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See *In re Armbruster*, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975). The issue remains the lack of adequate written description in the instant application, not whether other antibodies have been or could be made according to the disclosure. "It is not a question whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure of the application. Rather, it is a question whether the application necessarily discloses that particular device." *Id.* at 536. *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (Fed. Cir. 2004).

The following is reiterated for convenience. The claims are drawn to a pharmaceutical comprising a therapeutic antibody being modified with a peptide that reduces binding of the antibody to the therapeutic target and is effective for reducing an immune response against the antibody and for producing a therapeutic effect by binding to the therapeutic target. Thus, the claims encompass an extremely large genus of therapeutic antibodies linked to a genus of peptides, disclosed for treating, preventing and/or reducing any disease condition or disorder. However, written description of the present application only reasonably conveys a therapeutic humanized anti-CD52

antibody, CAMPATH-1H, modified by linking two different peptides, CD52 mimotope (QTSSPSAD) or CD52 mimotope mutant 9 (QTSAAAVD) in which the antibody-mimotope conjugate reduced the immune response (i.e., cytokine release) and had a therapeutic effect by binding CD52. Applicants' reliance on the description of a single species of humanized anti-CD52 antibody, CAMPATH-1H, modified by linking a CD52 mimotope (QTSSPSAD or QTSAAAVD) and having the properties and characteristics unique to the CAMPATH-1H-CD52 mimotope (QTSSPSAD or QTSAAAVD) interaction is not representative of the entire genus because the genus is highly variable, inclusive to a variety of therapeutic antibodies, having different therapeutic targets, functions and effects (i.e., agonistic, antagonistic, blocking, recruitment of effector cells, ect) and which are linked to any peptide, inclusive to peptides of varying lengths and chemical composition. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). The specification provides no other structural description of a therapeutic antibody being modified with a peptide that reduces binding of the therapeutic antibody to a therapeutic target, wherein the therapeutic antibody-peptide pair is effective for reducing an immune response against the antibody and produces a therapeutic effect by binding to the therapeutic target, other than the ones specifically exemplified; in essence the specification simply directs those skilled in the art to go figure out for themselves what the claimed genus of therapeutic antibody-peptide pairs look like. A description of what a material does, rather than what it is, usually does not suffice. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Clearly, one of skill in the art would not recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the single disclosed CAMPATH-1H-mimotope species. Therefore, only the humanized anti-CD52 antibody, CAMPATH-1H, linked to the CD52 mimotope QTSSPSAD or QTSAAAVD, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph and the rejection is maintained.

10. The rejection of claims 1, 6-10, 12-15 and 17 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising CAMPATH-1H (humanized anti-CD52 antibody), modified by linkage to a CD52 mimotope selected from QTSSPSAD and QTSAAAVD, does not reasonably provide enablement for all other therapeutic proteins and therapeutic antibodies modified (i.e., bound or linked) with just any other peptide or molecule (i.e., compound), wherein the therapeutic protein or therapeutic antibody has reduced side effects and produces a therapeutic effect by binding to the therapeutic target is maintained.

The response filed 12/19/2008 again asserts that one skilled in the art would know how to modify antibodies other than CAMPATH-1H in accordance with the present invention. Applicant again argues that one skilled in the art could determine by routine experimentation how to bind peptides to antibody combining sites of other antibodies to provide modified antibodies and then one could test the modified antibody to determine whether binding the therapeutic target has been reduced. Applicant also states that the fact that not every modified antibody is within the scope of the claimed invention does not mean that the present invention is not enabled. Applicant asserts that the examiner has confused the fact that not all modified antibodies are within the scope of the present invention with the legal standard for enablement. Applicant also points out that the examiners statement that even minor changes in an epitope sequence may effect antigen binding function has no relevance with respect to

enablement. Applicants' arguments have been fully considered but are not found persuasive for reasons already of record and reiterated herein for convenience. As an initial matter, the examiner acknowledges that the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984). Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable. However, claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971). In the instant case, the claims encompass a large genus of therapeutic antibodies and peptide pairs, wherein just any peptide reduces binding of just any therapeutic antibody to a therapeutic target, reduces side effects caused by the therapeutic antibody and produces a therapeutic effect by binding to the therapeutic target, encompassing significant numbers of inoperative species as evidenced by the art. For example, Lederman et al (Molecular Immunology 28:1171-1181, 1991, cited on PTO-892 mailed 8/4/06) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Li et al (Proc. Natl. Acad. Sci. USA 77:3211-3214, 1980, cited on PTO-892 mailed 8/4/06) disclose the dissociation of immunoreactivity from other activities when constructing analogs (see entire document). Therefore, even one amino acid difference in the peptide used for the modification of the therapeutic antibody could dramatically change the affinity or binding to the antibody combining site. Applicants' argument that the above examiner's statement pertaining to the fact that one amino acid difference in the peptide used for

the modification of the therapeutic antibody could dramatically change the affinity or binding to the antibody combining site has no relevance with respect to enablement is curious given that one of the Wands factors for determining whether a disclosure meets the enablement requirement is the predictability or unpredictability of the art. Thus, given that the claims are directed to a large genus of peptides and therapeutic antibodies, wherein the claimed invention depends antibody-antigen (e.g., peptide) interactions, the teachings of Lederman and Li are relevant to the presently claimed subject matter and the unpredictability within the large genus of modifying an antibody with just any peptide, such that the peptide modifies the therapeutic antibody to reduce binding to the therapeutic target, reduces side effects caused by the therapeutic antibody and produces a therapeutic effect by binding to the therapeutic target. Again, applicants' 'proof of concept', which is specific to the unique binding properties of the CAMPATH-1H antibody and CD52 function, could not be predictably extrapolated by those skilled in the art to the genus of peptides for modifying the genus of therapeutic antibodies or even for a particular therapeutic antibody. Applicant has not provided any guidance or direction as to how the properties of the CAMPATH-1H-CD52 mimotope interaction are predictive of the interaction between a particular therapeutic antibody and a given peptide sequence, such that the peptide modifies the therapeutic antibody to reduce binding to the therapeutic target, reduces side effects caused by the therapeutic antibody and produces a therapeutic effect by binding to the therapeutic target. There is insufficient evidence or nexus between the properties of the CAMPATH-1H-CD52 mimotope interaction and making and using any other therapeutic antibody bound to just any peptide that inhibits binding of the therapeutic antibody to the therapeutic target, reduces an immune response against the therapeutic antibody, and wherein the antibody produces a therapeutic effect by binding to the therapeutic target. The specification does not enable the genus because where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166

USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one particular species, what other species will work. See MPEP 2164.03. As stated in the MPEP: once the examiner has advanced a reasonable basis for questioning he adequacy of the disclosure, it becomes incumbent on the applicant to rebut that challenge and factually demonstrate that his/her application disclosure is in fact sufficient (MPEP 2164.05). It should be noted also that it is not opinion evidence directed to the ultimate legal question of enablement, but rather factual evidence directed to the amount of time and effort and level of knowledge required for the practice of the invention from the disclosure alone which can be expected to rebut a prima facie case of nonenablement. *See Hirschfield*, 462 F. Supp. at 143, 200 USPQ at 281. Therefore, the burden is upon the Applicants' to show objective evidence for other members of the genus of a therapeutic antibody modified by a peptide that reduces binding to a therapeutic target, reduces side effects caused by the antibody and produces a therapeutic effect by binding to the therapeutic target.

In view of the broad scope of the claims at issue, the lack of the predictability of the art to which the invention pertains as evidenced by Lederman et al and Li et al, the lack of guidance and direction provided by applicant, and the absence of working examples, undue experimentation would be required to practice the claimed pharmaceutical comprising a therapeutic antibody bound or linked to a peptide that inhibits binding of the therapeutic antibody to the therapeutic target, reduces side effects caused by the therapeutic antibody, and produces a therapeutic effect by binding to the therapeutic target with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed pharmaceutical and absent working examples providing evidence which is reasonably predictive that the claimed pharmaceutical comprising a therapeutic antibody bound or linked to a peptide inhibits binding of the therapeutic antibody to the therapeutic target, reduces side effects caused by the therapeutic antibody, and produces a therapeutic

effect by binding to the therapeutic target, commensurate in scope with the claimed invention.

For these reasons and those already of record the rejection is maintained.

11. The rejection of claims 1, 6, 9-10 and 17 under 35 U.S.C. 102(b) as being anticipated by Hale G (Immunotechnology, 1:175-187, 1995, cited on PTO-892 mailed 8/4/2006) is maintained.

In response to applicants' query at pg. 5 of the response, the statement at pg. 3 of the Advisory Action, i.e., "Applicants' attention is directed to the fact that claim 9 is not anticipated by Hale." was a typographical error in that claim 9 has always been included in the instant rejection. The previous statement made in the Advisory Action was intended to state claim 8 and not claim 9. Regardless, the point of the statement was to convey to applicant that an amendment to claim 1 which incorporates a limitation of a non-rejected claim would overcome the instant rejection, particularly in view that Hale never links the mimotope to the antibody.

The response filed 12/19/2008 states that the Campath antibodies of Hale were not modified, whereas Applicants' have modified an antibody with a peptide in order to inhibit binding of the antibody to a therapeutic target, and to reduce side effects caused by the antibody. Hale does not disclose or even suggest such a modified antibody. Applicant also states that the preamble of claim 1 defines the present invention as a "pharmaceutical" and states that the term "pharmaceutical" provides a further positive limitation to claim 1 that gives "life and meaning" to the claimed invention, citing various case law for support. Applicants' arguments have been fully considered but are not found persuasive. The modification with which applicant argues, i.e., linking a peptide to the antibody is not recited in the rejected claims, this recitation occurs in non-rejected claim 8. Again, the claims do not distincguish the modified antibody over the antibody of Hale. The claims merely require the antibody be modified with a peptide that reduces binding of the antibody to the therapeutic target, wherein the antibody includes an

antibody combining site that binds to the therapeutic target and said peptide is bound to the antibody combining site of said antibody. Thus, the CAMPATH-1H humanized antibody bound to the synthetic peptide, QTSSPSAD, is effective for reducing an immune response against the antibody and for producing a therapeutic effect by binding to the therapeutic target, does not distinguish the claimed therapeutic antibody bound to a peptide that inhibits binding of the antibody to a therapeutic target, from the anti-CD52 humanized antibody, CAMPATH-1H, reversibly bound by the synthetic peptide, QTSSPSAD, a CD52 mimotope that inhibits binding of CAMPATH-1H to human lymphocytes expressing CD52 (i.e., "therapeutic target") by about four fold.

In response to applicant's arguments that the preamble of claim 1 recites a “pharmaceutical”, the recitation “pharmaceutical” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As discussed supra, the antibody modified with a peptide that reduces binding of the antibody to the therapeutic target (e.g., by about four fold), wherein the antibody includes an antibody combining site that binds to the therapeutic target and said peptide is bound to the antibody combining site of said antibody of Hale is the same as the presently claimed the antibody also modified with a peptide that reduces binding of the antibody to the therapeutic target, wherein the antibody includes an antibody combining site that binds to the therapeutic target and said peptide is bound to the antibody combining site of said antibody and Hale also teaches the antibody in various buffers including buffered saline (PBS), which is reasonably interpreted to be a "pharmaceutically acceptable carrier". Hence, the

recitation of the intended use as a "pharmaceutical" does not result in a structural difference between the claimed invention and the prior art sufficient for patentability.

For these reasons and those already of record, the rejection is maintained.

12. No claim is allowed.

13. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643